4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0873]

Patrick Charles Bishop: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Patrick Charles Bishop for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Bishop was convicted of one felony count under Federal law for conspiracy to commit fraud. The factual basis supporting Mr. Bishop's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Bishop was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. Mr. Bishop provided notice to FDA that he acquiesced to the debarment; FDA received that notice on January 4, 2022. As such, his debarment commenced on the date FDA was notified of acquiescence.

DATES: This order is applicable January 4, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance. On July 9, 2021, Mr. Bishop was convicted, as defined in section 306(l)(1) of FD&C Act, in the U. S. District Court for the Northern District of Alabama, when the court entered judgment against him for the offense of conspiracy to commit fraud, in violation of 18 U.S.C. 371.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the plea agreement in Mr. Bishop's case, filed on January 7, 2021, in which he pleaded guilty, he owned Patrick, LLC and employed other individuals. Using the business name "Best Peptide Supply, LLC," he ordered PNC-27 from GL Biochem (Shanghai), Ltd., a supplier based in China, and used the PNC-27 to manufacture drug products intended for the treatment of cancer in humans. FDA has not approved PNC-27 for use in the United States as a drug to treat any disease, including any form of cancer. He obtained PNC-27 under the false pretense that he intended to use the product solely for laboratory research purposes. In fact, he provided invoices to GL Biochem that did not use the term "PNC-27" and included the statement "FOR RESEARCH ONLY." He falsely certified to GL Biochem that the product he was purchasing from GL Biochem was "restricted to laboratory research purposes, excluding clinical research on [the] human body."

Mr. Bishop also falsely represented to FDA personnel that the product shipped from GL Biochem was to be used for laboratory testing and scientific research. Mr. Bishop directed GL Biochem to ship the PNC-27 to his residences and other locations in the State of Alabama where he used the PNC-27 he purchased to manufacture drug products intended for human use to treat cancer. Specifically, along with others, Mr. Bishop knowingly caused PNC-27 to be processed

into a "water-based PNC-27 drug product" as well as suppositories using methods, controls, and facilities that did not conform to current good manufacturing practice. Mr. Bishop sold and distributed the unapproved, misbranded, and adulterated PNC-27 drug products he manufactured to individuals in other States and countries; these drug products failed to bear directions for use, and some bore no labeling whatsoever. To avoid detection by FDA and to conceal the nature of these unapproved, misbranded, and adulterated drug products, Mr. Bishop operated under the business name "Immuno Cellular Restoration Program, Inc. (ICRP)" and used the terms, "research," "sample," "ICRP" and "ICRPstudy.com" on his product labels and shipping documentation. Mr. Bishop received millions of dollars in payments for his unapproved, misbranded, and adulterated PNC-27 drug products.

As a result of this conviction, FDA sent Mr. Bishop, by certified mail, on October 18, 2021, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Bishop's felony conviction for one count of conspiracy to commit fraud was for conduct relating to the importation into the United States of any drug or controlled substance because he conspired to illegally import, manufacture, and distribute in interstate commerce unapproved, misbranded, and adulterated drug products while concealing this conduct from Federal authorities in violation of 18 U.S.C. 371. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Bishop's offense and concluded that the felony offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Bishop of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Bishop received the proposal and notice of opportunity for a hearing on October 25, 2021. Mr. Bishop sent a

memorandum to FDA, dated November 3, 2021, wherein he stated that he acquiesced to the proposed debarment. FDA received the memorandum on January 4, 2022. In accordance with section 306(c)(2)(B) of the FD&C Act, Mr. Bishop's period of debarment shall commence on the date FDA received notice he acquiesced to the debarment, which was January 4, 2022 (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Patrick Charles Bishop has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Bishop is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective January 4, 2022. Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Bishop is a prohibited act.

Any application by Mr. Bishop for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-0873 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: February 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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